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CRR Project Proposal, August 2019
Assessing the utility of acetaminophen post-operatively in the intensive care unit

Study Purpose and Rationale:
Pediatric post-operative sedation and pain management is a topic of much interest among clinicians across multiple subspecialties. In one example, opioid exposure in critically ill pediatric patients is a target of study for Pediatric Critical Care Medicine, Anesthesiology, and Surgery. An active area of research is the question of how these medications affect neurodevelopment. In an effort to optimize pain control while limiting exposure to opioid, benzodiazepines and anesthetics, institutions have implemented comfort algorithms and quality improvement initiatives for this patient population with goals to reduce exposure to these medications. These efforts have reported a variety of benefits, most commonly PICU length of stay, frequency of unplanned extubation, prevalence of patients experiencing drug withdrawal, total sedation duration, and doses. One medication utilized to reduce pain and limit opioid use is intravenous acetaminophen. This study aims to explore outcomes related to implementation of a post-operative pain protocol that includes standing acetaminophen orders.

Study Design and Statistical Analysis:
This is a retrospective observational study of post-operative pediatric cardiac surgical patients prior to, and after, the implementation of standing acetaminophen in the 24 hours post-operatively for patients at Columbia University Medical Center. EHR data will be extracted from the Tripartite Request Assessment Committee (TRAC) at Columbia. Members of the study team have previously worked with this data and have extensive experience in ensuring privacy and confidentiality of electronic data. The team will follow all CUMC and NYP guidelines regarding information security. We will look at recorded data in the EHR to evaluate for our primary outcome such as total number of opioid medication doses, opioid medication infusion rates, and total duration of opioid medication therapy as a representation of opioid exposure. We will also look at recorded data in the EHR including total number of acetaminophen medication doses, total number of NSAID medication doses, intensive care unit length of stay, duration of mechanical ventilation, laboratory markers including creatinine and hepatic function panels, and pain scores as secondary outcomes. We will compare differences in patient outcome parameters as mentioned between the two datasets (pre and post) and assess for meaningful and/or significant associations.

We anticipate a 3-month pre-intervention period and 3 month post-intervention period to compare baseline data. An estimated 85 will be studied in the pre-intervention period and 85 patients will be studied in the post-intervention period. The cohort may further be subdivided by age, sex and procedure in order to identify patterns. An example statistical analysis for the primary outcome of days on opioid treatment will use unpaired t-test. With a standard deviation of number of days of opioid therapies about 0.5 day, we anticipate to be able to detect an effect

size of about 0.22 days (~6 hrs). This amount of time is clinically significant for discharge or transfer out of the ICU.

Study Subjects:
All patients admitted to the pediatric intensive care units after cardiac surgery will be included.

Study Procedure: No procedures will be performed in this study.

Study Drugs: No study drugs, approved or investigational, will be given in this study.

Medical Device: No medical devices will be used in this study.

Study Questionnaires: No questionnaires will be used in this study.

Confidentiality of Study Data:
All research data will be stores on a CUMC server. Data in result sets for analysis in statistical software will be stripped of PHI. Any connection between PHI and the data set will be maintained in a password-protected file stored on CUMC a CUMC server. Access to the data will be limited to those individuals listed on the IRB protocol. The team will periodically meet to ensure confidentiality of the data, including changing user passwords in compliance with CUMC IT policies.

Potential Conflict of Interest: None of the investigators have any conflicts of interest to report.

Location of the Study: The study will take place at the Morgan Stanley Children's Hospital pediatric intensive care unit on 9 Tower.

Potential Risks:
As this is an observational study on data collected during routine clinical care, there is no effect on patient care. This research is unlikely to provide pertinent information relevant to the individual subjects, however if this does arise we will make the effort to communicate this. This study required the use of identifiable patient information to link between databases (TRAC and cardiac registry) so that demographics and diagnoses can be appropriately attributed. Identifiable information such as birth date will be used to calculate patient age, which in pediatrics is required to contextualize laboratory values, medication dosages. Privacy will be maintained as above.

Potential Benefits:
As this is a retrospective and prospective review of existing data, there will be no direct benefit to patients whose data are analyzed. Results from this study may allow us to find more efficient and effective pain management strategies.

Alternative Therapies: There will be no experimental therapies employed in this study.

Compensation to Subjects: No compensation will be provided to the study subjects.

Costs to Subjects: The patients will not incur additional costs as a result of participating in this study.

Minors as Research Subjects:
Because this is a retrospective study on data collected during routine care of hospitalized children, the risk is minimal, only that of PHI leak. We anticipate that most children will be in the intensive care unit and will either by medically too ill to assent or too young. No parental permission will be obtained because the involvement of children in this research meets criteria for a complete waiver of consent.

This research is even more important in the pediatric population where exposure to opioid medications can affect neurodevelopmental outcomes. Etiologies of pediatric cardiac surgery differ from those in the adult population, as do co-morbid conditions so understanding adult datasets is inadequate on its own to extrapolate to pediatrics. Thus the pediatric intensive care units will be targeted for data extraction and analysis.

Radiation or Radioactive Substances: This study will not employ radiation or radioactive substances.

References:

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